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Description

BACKGROUND OF THE INVENTION

This invention relates to body implantable medical devices, and more particularly to implantable electrodes for sensing electrical impulses in body tissue or for delivering electrical stimulation pulses to an organ, for example for pacing the heart or arresting tachycardia or cardioversion.

Cardiac pacing leads are well known and widely employed for carrying pulse stimulation signals to the heart from a battery operated pacemaker or other pulse generating means, as well as for monitoring electrical activity of the heart from a location outside of the body. More recently, electrodes have been used to stimulate the heart in an effort to terminate tachycardia or other arrhythmias. In all of these applications, it is highly desirable to minimize the electrical impedance at the interface between the electrode and body tissue.

A direct approach to reducing interface impedance is to increase the electrode surface area, which is subject to practical limits for maximum electrode size. Increasing the number of reactive sites in an electrode improves its ability to convert an electronic current to an ionic current. As used in this application, the term "impedance" relates to the conversion of electronic current to ionic current.

One particularly effective means of increasing reactive surface area is to form a highly porous electrode body, for example as disclosed in U.S. Patent No. 4,011,861 (Enger), and in U.S. Patent No. 4,156,429 (Amundson). The Amundson Patent discloses a porous electrode formed by a bundle of fibers, preferably of platinum but alternatively of Elgiloy, titanium, or a platinum iridium alloy. The fibers are compressed into a bundle, then heated to a sufficient temperature and for a sufficient time to sinter the fibers. The fibers or filaments may be bundled within a metallic screen or grid, and preferably form between about three percent and thirty percent of the electrode volume, with the balance of the volume open. This macro porosity enhances ingrowth of tissue to stabilize the electrode, and the increased surface area to volume ratio lowers interface impedance, improving both sensing and pacing performance.

Other approaches to increasing electrode efficiency concern reducing fibrosis, i.e. formation of a capsule of inactive tissue that surrounds and isolates the electrode from active tissue. The resultant increase in distance from the electrode to viable tissue increases the voltage required to generate the same transmembrane potential. In U.S. Patent No. 4,281,668 (Richter et al), a vitreous carbon or pyrolytic carbon electrode is superficially activated, e.g. by oxidation, for micro porosity. The electrode

then is coated with a body compatible, ion conducting and hydrophobic plastic. This approach is said to substantially prevent thrombus formation.

U.S. Patent No. 4,603,704 (Mund et al) discloses an electrode including a hemispherical head of platinum or titanium. A porous layer is coated over the head, either by vapor deposition or by magnetron sputtering. The porous layer consists of a carbide, a nitride or a carbonitride of at least one of the following metals: titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten.

U.S. Patent No. 4,542,752 (DeHaan et al) features an implantable lead with a core of platinum, titanium or similar metal, covered with a porous sintered titanium alloy, which in turn is covered with a porous carbon lattice. The porous carbon surface is said to promote tissue ingrowth and provide low polarization impedance.

In U.S. Patent No. 4,407,302 (Hirshorn et al), the external surface of a cardiac pacer electrode tip is provided with a concavity and roughened over its exterior, for example by abrading with a jet of glass beads, to increase the micro surface area of the electrode tip and reduce the sensing impedance of the tip. At the same time, the concave area in an otherwise convex surface of the electrode tip is said to significantly and advantageously increase the pacing impedance. The underlying theory of this approach, with respect to pacing impedance, is that higher resistance reduces the current flow for a given voltage, and consequently reduces the energy involved in pacing.

An example of a porous electrode tip is found in U.S. Patent No. 4,577,642 (Stokes), in which the electrode is formed by sintering spheres or other particles of metal resulting in formation of molecular sieves which control the elution rate of a drug housed in the lead distal end. This approach, however, requires a balancing between a relatively large reactive surface area and pore size of the structure. Sintering small spheres enhances surface area but reduces porosity. Conversely, sintering of larger spheres results in a more porous structure with lower surface area. In any event, maximum theoretical porosity is under fifty percent, and the pores or passages typically are tortuous and convoluted.

Despite the varying degrees of success of the above approaches, polarization losses and after potentials remain significant problems to electrode efficiency. Depending on applied potential and pulse duration, activities at the electrode interface range from reorganization of ions to electrolysis. As current densities increase, these reactions change the ionic concentration at the interface, requiring migration of ions from increasingly greater distances. The energy required to reorient and move

the ions is the measure of the polarization loss of the electrode, and represents wasted energy for a loss in efficiency. The source of the after potential is the concentration gradient or residual charge at the end of a pulse.

The present invention overcomes these problems by providing a body implantable electrode having an electrode body as set out in Claim 1. The precharacterising part of Claim 1 is based on US-A-4156429, and the distinguishing features of the present invention are set out in the characterising part of Claim 1.

The electrode of the present invention has substantially reduced polarization loss, and reduced capacitive coupling at the electrode/tissue interface, thereby reducing signal distortion.

The electrode also has reduced after potential, thus reducing the refractory period and reducing sensing delays following stimulating pulses.

In one embodiment, an intravascular pacing lead including the electrode, has a reduced chronic threshold, improved pulse sensing capability and shorter recovery time for sensing after stimulation pulses. The electrode includes a surface texture comprising multiple surface irregularities formed over substantially the entire exposed surface of the electrode body. The irregularities are in sufficient size and density to substantially increase the surface area of the exposed surface, as compared to an equivalent surface area for an identically sized filament structure with a smooth, non-textured surface.

A salient feature of the present invention is that texture penetrates deeply into and throughout the electrode body. The penetrating texture yields a dramatic increase in reactive surface area, from one to two orders of magnitude greater than the equivalent reactive surface area for a nontexturized electrode. The microscopic texturing of a macroscopically porous lead body, in accordance with the present invention, dramatically reduces the pacing impedance as well as the sensing impedance, which contradicts the theory mentioned above in connection with the Hirshorn patent. It has been found, however, that reduced pacing impedance (by elimination of polarization losses) increases the ratio of bulk impedance to the total impedance as measured between the pacing electrode and the indifferent signal return electrode. Thus, more of the voltage drop occurs across tissue, where it is useful for causing stimulation, with proportionately less of the drop occurring at the electrodes, where it is non-productive. This permits a reduction in the overall potential or pulse duration, in either event reducing the pacing energy required.

The electrode body has passages, a substantial proportion of which have diameters properly

sized to promote extensive fibrous ingrowth, which tends to securely anchor the implanted electrode and stabilize the electrode/tissue interface. The relatively large size of the electrode passages further promotes use of interior electrode surfaces, as well as the exterior surface, for the conversion of an electronic current into an ionic current. This reduces polarization losses without increasing the geometric size of the electrode. In combination, the relatively large passages to the electrode interior, and the micro texturizing of both the electrode's exterior and interior surfaces, substantially reduce electrode interface impedance for more effective stimulation pulsing and sensing of electrical pulses generated in proximate tissue.

IN THE DRAWINGS

For a better understanding of the above and other features and advantages, reference is made to the drawings in which:

Figure 1 is a side sectional view of a cardiac pacing lead constructed in accordance with the present invention;

Figure 2 is a photograph of a magnified image of part of an electrode of the pacing lead of Figure 1, obtained using a scanning electron microscope;

Figure 3 is a photograph of a further enlarged image of the electrode, again obtained with a scanning electron microscope;

Figure 4 is a sectional view of a filament of the electrode, illustrating the layers applied to a platinum wire to provide a desired texture;

Figure 5 is a sectional view similar to Figure 2, illustrating an alternative texturizing approach;

Figure 6 is a sectional view similar to that in Figure 2, showing another alternative texturizing approach;

Figure 7 is a side elevation of a ring electrode constructed in accordance with the present invention;

Figure 8 is a top plan view of a patch electrode constructed in accordance with the present invention; and

Figure 9 is a side elevation of the electrode of Figure 8.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, there is shown in Figure 1 the distal end region of an implantable cardiac pacing lead 16. Devices such as lead 16 typically are inserted intravenously, for example into the subclavian vein, or the cephalic vein, and progressively moved toward the heart until the distal end reaches a selected cardiac chamber. With

the distal tip positioned at a selected location, the lead proximal end, still outside the body, is maneuvered to implant the distal tip into the endocardium. The implanted lead transmits electrical signals between the selected location in the heart and the lead proximal end, for one or both of two purposes:

- (a) to monitor the heart's electrical activity at the selected location; and
- (b) to carry stimulating signals to the selected location from a pulse generator (not shown) connected to the lead's proximal end.

To transmit the electrical signals there is provided an electrical conductor, shown in Figure 1, as a single wound coil 18 formed of a nickel chromium alloy. The coil provides maximum flexibility for conforming to the vein, with minimal stress to the conductor. At the distal end of the lead is an electrode 20, electrically and mechanically coupled to coil 18 by a platinum alloy crimp tube 22. A flexible, dielectric sheath 24 surrounds the coil and crimp tube. The sheath is formed of a biocompatible material such as silicone rubber. A plurality of tines 26 are formed as part of sheath 24 near its distal end, and are employed to secure the lead's distal end to the selected endocardial location.

Electrode 20 is constructed of platinum or a platinum alloy, stretched to a thin wire 28, then crumpled and packed against the distal end of crimp tube 22. The wire has a diameter of at least five microns, and more preferably about 100 microns. A platinum alloy screen 30, fastened to the periphery of the crimp tube's distal end, maintains the bundled platinum alloy wire in place. The wire and screen are heated to a sufficient temperature and for a sufficient time to sinter portions of the wire and screen together, for example as explained U.S. Patent No. 4,156,429 (Amundson), incorporated herein by reference. So constructed, electrode 20 is highly porous, for example consisting of approximately twenty percent platinum or platinum alloy by volume, and substantially the remaining eighty percent being open to permit passage of bodily fluids through electrode 20 and to promote tissue ingrowth.

Crimp tube 22 is elongate and cylindrical, with a radially outward flange 32 at its distal end to serve as an abutment for sheath 24 and an anchor for screen 30. The distal end of conductor coil 18 is retained in the crimp tube by a core pin 34 and a crimp 36 in the crimp tube wall proximally of a radially enlarged head portion of the core pin.

The photograph of Figure 2 shows electrode 20 magnified sixty times, and was taken with a scanning electron microscope powered at ten kilovolts, employing secondary electron imaging. Wire 28 is surrounded by screen 30. By virtue of the screen and the sintering step, the wire is maintained in a highly serpentine winding. Nonetheless, interstitial

volumetric regions of open space, between adjacent portions of wire 28, combine to form multiple open passages throughout electrode 20. Many of these passages are relatively large, for example with average diameters of thirty microns or more. A preferred range in diameters is from ten to fifty microns, although the diameters may be as large as one hundred fifty microns. Typically, the open volumetric regions comprise from seventy to ninety-five percent of the volume of electrode 20. The large proportional volume and size of the passages result in a macro porosity in electrode 20 which allows passage of bodily fluids through electrode 20 and promotes extensive tissue ingrowth.

The photograph of Figure 3 illustrates a portion of wire 28 magnified 1,400 times with the aid of a scanning electron microscope powered at ten kilovolts, employing back-scattering electron imaging. The nodules are generally smooth and tend to be oblong rather than spherical, yet are generally uniform in average diameter, in the range of about one to two microns, as is apparent from the white horizontal bar in the photograph indicating a length of ten microns. Pores or indentations between nodules likewise are approximately one or two microns in average diameter. The nodules can, however, have an average diameter of less than four microns.

The nodules, indentations and other surface irregularities of course have virtually no impact on the geometric surface area, i.e. the exterior surface area of an identically sized electrode having a smooth exterior surface, which determines current density for stimulation. However, they have a substantial and surprising impact on the real surface area and the reactive surface area. In this context, the real surface area is the total fluid to metal interface, which includes interior surface areas along passageways as well as the exterior surface. The reactive surface area is the proportion of the real surface area available for converting electronic current to ionic current. For example, in an electrode having a 7.5 square mm profile, the real surface area is approximately 500 square mm. Further, comparison of electrode 20 with a similar packed wire electrode having no texturizing treatment yielded a fifteen-fold improvement in charge transfer, a seventy-eight percent reduction in polarization losses, and a seventy-four percent decrease in the after potential at the electrode interface, all indicative of substantially increased reactive surface area. Generally, the increase in reactive surface area has been found to be at least an order of magnitude, more particularly from ten to one hundredfold.

In accordance with the present invention, electrode 20, particularly along the entire exposed outer surface of wire 28 and screen 30, is texturized

or treated to provide multiple surface irregularities, thus to increase the surface area of the exposed outer surface by from one to two orders of magnitude. Surface texturizing is achieved by vapor deposition, magnetron sputtering, ion impregnation or similar type of process, for convenience broadly referred to as glow discharge processes, either alone or in combination with electroplating. In particular, a high energy, low temperature vapor deposition process, at an argon pressure of about 1.333×10^2 Pa (one torr) or less, has been found satisfactory in applying the layers necessary for texturizing wire 28 and screen 30.

One preferred approach is illustrated in Figure 4, and involves forming surface irregularities by glow discharge or vapor deposition, after a wire such as wire 28 has been sintered. More particularly, an underlayer 38 of titanium is sputtered onto a wire 40 to a thickness of from 20,000 to about 35,000 Angstroms (2 to 3.5 microns). The primary purpose of underlayer 38 is to provide the desired texture, in the form of multiple nodules or adhering particles. The particles are somewhat elongate and irregular, but in general have average diameters ranging from one to two microns. Underlayer 38 also serves as an adhesion layer for a layer 42 of platinum. Platinum layer 42, sputtered to a thickness of approximately 15,000 to 20,000 Angstroms, is applied to reduce the activation energy and enhance biocompatibility. If desired, a thin outer layer 44 of carbon is sputtered onto the platinum layer, preferably to a thickness in the range of 1,500 to 2,000 Angstroms, to further enhance biocompatibility of the electrode.

Figure 5 illustrates an alternative texturized filament in which a platinum wire 46 is coated by sputtering or vapor deposition with an underlayer 48 of titanium to a thickness of approximately 8,000 Angstroms. In this alternative approach, titanium layer 48 is used only for adhesion. A platinum texturing layer 50 is then applied to the titanium layer in a process involving multiple platings of platinum-black, preferably in the range of from eight to fifteen applications for a thickness of 30,000 to 150,000 Angstroms. Following each electroplating of platinum-black, the electrode is baked at approximately 650 degrees C. for about twenty minutes, to enhance adhesion. The multiple applications result in a texture for the platinum-black layer in the form of multiple particles or nodules, again with average diameters equal to or less than two microns.

Figure 6 illustrates yet another approach, in which the first layer applied to a platinum wire 52 by sputtering or vapor deposition, is an underlayer 54 approximately 8,000 Angstroms thick, preferably of titanium. Underlayer 54 is provided principally to ensure proper adhesion of the next subsequent

layer, a texturizing layer 56 preferably aluminum. Layer 56 is applied by vapor deposition over the titanium underlayer to a thickness of approximately 40,000 Angstroms. The aluminum, when so applied, forms multiple nodules or adhering particles. The particles are somewhat elongate and irregular, but generally have average diameters of from one to two microns. The aluminum texture layer is deposited in an argon or other inert gas atmosphere, thus to form multiple indentations or pores about one micron in diameter for further texturizing the aluminum layer.

The size of the nodules and pores, however, is not so critical as the fact that in combination they substantially increase the area of the platinum wire exposed surface by between one and two orders of the electrode.

Following aluminum deposition, a platinum layer 58 is applied over the aluminum layer by vapor deposition, to a thickness of approximately 20,000 Angstroms. While platinum and platinum-black are preferred, this layer may be formed of platinum, iridium, ruthenium or alloys or compounds of these constituents, their salient characteristics being a catalytic nature and low activation energy.

Other approaches, satisfactory although somewhat less preferred, include a Raney platinum process whereby high energy deposition techniques are used to impregnate the platinum electrode surface with extremely fine aluminum particles. Subsequently the aluminum particles are dissolved in an acid bath, leaving multiple, minute indentations to provide the desired surface texture.

Sputter etching and sputter coating in an atmosphere that includes oxygen may serve to provide the required texture.

Finally, although not essential, a cover layer 60 of carbon may be applied over the outer platinum layer, to a thickness in the range of from 1,500 to 2,000 Angstroms, to further enhance the biocompatibility of the electrode.

Figure 7 shows an intermediate portion along the length of an intravascular lead 62 including a conductor coil 64 contained within a dielectric sheath 66. Also surrounding the coil and interrupting the continuity of sheath 66 is a ring electrode 68 including a platinum wire 70 packed into an annular configuration between an outer wire mesh screen 72 and an electrically conductive tube 74. Wire 70 is treated to enhance its surface texture in the same manner as wire 28 of electrode 20. Alternatively, a perforated or slotted outer casing may contain wire 70. Again, surface texturizing is accomplished after initial formation of the electrode, including sintering as previously described.

Figure 8 and 9 show a patch electrode 76 used in defibrillation or cardioversion, formed by interwoven, mutually perpendicular strands of platinum

or titanium wire 78 and 80, and a conductor 82 for transmitting electrical signals to and from electrode 76. As seen from Figure 9, patch electrode 76 may include several levels of perpendicular strands, with a finer, stretched and packed platinum wire 84 contained between separate layers, and microtexturized over exterior and interior surfaces as described above.

Thus, in accordance with the present invention a variety of body implantable electrodes are formed with a combined macro porosity and micro texturizing, for a substantial increase in reactive surface area, enhanced ingrowth of tissue for improved electrode stabilization, and reduced interface impedance. Polarization loss is markedly reduced to improve signal quality, and shorten the refractory period after a stimulating pulse is reduced to enable a more rapid sensing of tissue response

Claims

1. An electrode implantable inside a patient, comprising:
 - an electrode body (20,68,76) constructed of an electrically conductive filament structure including a plurality of elongate fiber elements (28,70,84) with diameters of at least five microns, said fiber elements packed in close proximity with one another and forming multiple passages throughout the electrode body and open to the exterior of the electrode body, whereby an exposed surface of the elongate fiber elements includes an interior surface portion along and defining said passages and an exterior surface portion defining the exterior surface of the electrode body, with the volume occupied by the passages comprising more than one half of the total volume occupied by the electrode body;
 - characterized by a surface texture comprising multiple surface irregularities formed over substantially the entire exposed surface of the elongate fiber elements, thereby to substantially increase the surface area of said exposed surface as compared to an equivalent smooth surface of an identically sized electrode body.
2. The implantable electrode of Claim 1 wherein:
 - at least some of the passages have diameters in the range of from ten to fifty microns, and the surface area of said exposed surface is greater than an equivalent smooth surface of an equally sized electrode body, by a factor of at least ten.
3. The implantable electrode of Claim 1 or 2 wherein:
 - said filament structure includes at least one strand of a metallic wire packed into a compress.
4. The implantable electrode of Claim 3 wherein:
 - said filament structure is a single strand of said metallic wire, said fiber elements (28,70,84) comprising portions of the single strand.
5. The electrode of Claim 3 or 4 wherein:
 - said irregularities are formed as a metallic texturizing layer (38,50,56) applied to said metallic wire.
6. The electrode of Claim 5 wherein:
 - said metallic texturizing layer (38,50,56) consists substantially of aluminium, platinum or titanium.
7. The electrode of Claim 5 or 6 wherein:
 - said texturizing layer (38,50,56) is applied by vapour deposition following the formation of said compress.
8. The electrode of any one of Claims 3 to 7 further including:
 - an adhesion enhancing underlayer (48,54) between said metallic wire and said texturizing layer.
9. The electrode of Claim 8 wherein:
 - said underlayer (48,54) consists substantially of titanium.
10. The electrode of any one of Claims 3 to 9 further including:
 - an inert metallic cover layer (42,58) over said metallic texturizing layer.
11. The electrode of Claim 10 wherein:
 - said cover layer is formed of a catalytic material having a low activation energy.
12. The electrode of Claim 11 wherein:
 - said catalytic material consists substantially of one of the following constituents: platinum, titanium, and a platinum-iridium alloy.
13. The electrode of Claim 12 wherein:
 - said catalytic material consists substantially of platinum and further including a carbon layer (44,60) vapor deposited over said platinum layer.

14. The electrode of any preceding claim wherein:
said irregularities include multiple nodules
having average diameters of less than about
four microns.
15. The electrode of Claim 14 wherein:
the average diameter of said nodules is
from one to two microns.
16. The electrode of Claim 15 wherein:
said irregularities further include depres-
sions having an average diameter of about one
to two microns.
17. The electrode of any preceding claim wherein:
said passages have average diameters in
the range of from about ten microns to about
one hundred and fifty microns.
18. The electrode of Claim 17 wherein:
said passages have average diameters in
the range of from ten to fifty microns.
19. The electrode of Claim 1, further including:
a flexible electrical conductor (18,64) and a
flexible, biocompatible, dielectric sheath
(24,66) surrounding said conductor along sub-
stantially the entire length thereof; and
a coupling means (22,74) for electrically
and mechanically joining the electrode body
with the conductor, said electrode body being
packed against the coupling means;
wherein at least some of the passages
have diameters in the range of ten to fifty
microns.
20. The electrode of Claim 1, further including:
a first layer of interwoven, mutually per-
pendicular strands (78,80) formed of a biocom-
patible, electrically conductive material;
wherein said electrode body is provided as
a second layer including said plurality of elon-
gate fiber elements (84) contained against said
first layer and said multiple passages are open
to said first layer; and
wherein said surface texture so increases
the surface area by a factor of at least five.
21. The defibrillation patch electrode of Claim 20
further including:
a third layer of interwoven, mutually per-
pendicular strands (78,80) formed of a biocom-
patible, electrically conductive material dispo-
sed opposite said first layer, with said second
layer contained between the first and third
layers.

22. The electrode of Claim 1 further including:
a conductor (18,64,82) electrically asso-
ciated with said electrode body for transmitting
electrical pulses from a selected area of body
tissue at which the electrode body is positiona-
ble, to a sensing location remote from said
selected area;
wherein said surface texture so increases
the surface area of said exposed surface by a
factor of at least five.

Patentansprüche

1. Eine in einen Patienten implantierbare Elektro-
de umfassend:
einen Elektrodenkörper (20,68,76) der aus
einer elektrisch leitenden Faserstruktur ein-
schließlich mehrerer länglicher Faserelemente
(28,70,84) mit Durchmessern von mindestens 5
µm aufgebaut ist, wobei die Faserelemente
dicht aneinander gepackt sind und mehrfache
Durchgänge durch den Elektrodenkörper bil-
den und zur Außenseite des Elektrodenkörpers
offen sind, wodurch eine freiliegende Oberflä-
che der länglichen Faserelemente einen Innen-
flächenabschnitt entlang der Durchgänge und
diese definierend sowie einen Außenflächenab-
schnitt, der die Außenfläche des Elektroden-
körpers definiert, umfaßt, wobei das durch die
Durchgänge eingenommene Volumen mehr als
die Hälfte des durch den Elektrodenkörper ein-
genommene Volumen umfaßt;
gekennzeichnet durch eine Oberflächen-
textur mit mehrfachen über im wesentlichen
der gesamten freiliegenden Oberfläche der
länglichen Faserelemente ausgebildeten Ober-
flächenunregelmäßigkeiten, um dadurch die
Oberflächengröße der freiliegenden Oberfläche
im Vergleich zu einer äquivalenten glatten
Oberfläche eines Elektrodenkörpers identi-
scher Größe erheblich zu vergrößern.
2. Die implantierbare Elektrode gemäß Anspruch
1, wobei wenigstens einige der Durchgänge
Durchmesser im Bereich von 10 bis 50 µm
aufweisen und die Oberflächengröße der frei-
liegenden Oberfläche um einen Faktor von
mindestens 10 größer ist als eine äquivalente
glatte Oberfläche eines gleichgroßen Elektro-
denkörpers.
3. Die implantierbare Elektrode gemäß Anspruch
1 oder 2, wobei die Faserstruktur mindestens
einen Strang eines in eine Kompressse bzw.
Packung gepackten metallischen Drahtes um-
faßt.

4. Die implantierbare Elektrode gemäß Anspruch 3, wobei die Faserstruktur ein einzelner Strang des metallischen Drahtes ist und die Faserelemente (28,70,84) Abschnitte des einzelnen Stranges umfassen.
5. Die Elektrode gemäß Anspruch 3 oder 4, wobei die Unregelmäßigkeiten als eine auf den metallischen Draht aufgebrachte metallische Texturschicht (38,50,56) ausgebildet sind.
6. Die Elektrode gemäß Anspruch 5, wobei die metallische Texturschicht (38,50,56) im wesentlichen aus Aluminium, Platin oder Titan besteht.
7. Die Elektrode gemäß Anspruch 5 oder 6, wobei die Texturschicht (38,50,56) durch Gasabscheidung nach der Bildung der Kompressen bzw. Packung aufgebracht wird.
8. Die Elektrode gemäß einem der Ansprüche 3 bis 7, weiterhin umfassend eine Adhäsions- bzw. Haftverbesserungsunterschicht (48,54) zwischen dem metallischen Draht und der Texturschicht.
9. Die Elektrode gemäß Anspruch 8, wobei die Unterschicht (48,54) im wesentlichen aus Titan besteht.
10. Die Elektrode gemäß einem der Ansprüche 3 bis 9 weiterhin umfassend eine inerte metallische Deckschicht (42,58) über der metallischen Texturschicht.
11. Die Elektrode gemäß Anspruch 10, wobei die Deckschicht aus einem katalytischen Material mit einer niedrigen Aktivierungsenergie gebildet ist.
12. Die Elektrode gemäß Anspruch 11, wobei das katalytische Material im wesentlichen aus einem der folgenden Bestandteile besteht: Platin, Titan und eine Platin-Iridium-Legierung.
13. Die Elektrode gemäß Anspruch 12, wobei das katalytische Material im wesentlichen aus Platin besteht und weiterhin eine Kohlen- bzw. Kohlenstoffschicht (44,60) umfaßt, die über der Platinschicht dampfabgeschieden ist.
14. Die Elektrode gemäß einem vorstehenden Anspruch, wobei die Unregelmäßigkeiten vielfache Klümpchen bzw. Knötchen mit durchschnittlichen Durchmessern von weniger als etwa 4 µm umfassen.
15. Die Elektrode gemäß Anspruch 14, wobei der durchschnittliche Durchmesser der Klümpchen bzw. Knötchen zwischen 1 und 2 µm beträgt.
16. Die Elektrode gemäß Anspruch 15, wobei die Unregelmäßigkeiten desweiteren Vertiefungen mit einem durchschnittlichen Durchmesser von etwa 1 bis 2 µm umfassen.
17. Die Elektrode gemäß einem vorstehenden Anspruch, wobei die Durchgänge durchschnittliche Durchmesser im Bereich von etwa 10 µm bis etwa 150 µm aufweisen.
18. Die Elektrode gemäß Anspruch 17, wobei die Durchgänge durchschnittliche Durchmesser im Bereich von 10 bis 50 µm aufweisen.
19. Die Elektrode gemäß Anspruch 1, weiterhin umfassend:
 - einen flexiblen elektrischen Leiter (18,64) und eine flexible, bio-verträgliche, dielektrische Umhüllung (24,66), welche den Leiter über im wesentlichen dessen gesamter Länge umgibt; und
 - eine Kupplungseinrichtung (22,74) zum elektrischen und mechanischen Verbinden des Elektrodenkörpers mit dem Leiter, wobei der Elektrodenkörper gegen die Kupplungseinrichtung gepackt ist; wobei mindestens einige der Durchgänge Durchmesser im Bereich von 10 bis 50 µm aufweisen.
20. Die Elektrode gemäß Anspruch 1, weiterhin umfassend:
 - eine erste Schicht geflochtener, zueinander senkrechter Stränge (78,80), die aus einem bio-verträglichen, elektrisch leitenden Material gebildet sind; wobei der Elektrodenkörper als eine zweite Schicht einschließlich der Mehrzahl länglicher Faserelemente (84) an die erste Schicht gebunden vorgesehen ist und die vielfachen Durchgänge zur ersten Schicht hin offen sind; und
 - wobei die Oberflächentextur die Oberflächengröße so mit um einen Faktor von mindestens 5 vergrößert.
21. Die (defibrillation patch) Elektrode gemäß Anspruch 20, weiterhin umfassend:
 - eine dritte Schicht geflochtener zueinander senkrechter Stränge (78,80) aus einem bio-verträglichen elektrisch leitenden Material, die gegenüber der ersten Schicht angeordnet ist, wobei die zweite Schicht zwischen der ersten und der dritten Schicht gehalten ist.

22. Die Elektrode gemäß Anspruch 1, weiterhin umfassend:

einen Leiter (18,64,82) der dem Elektrodenkörper elektrisch zugeordnet ist zum Übertragen von elektrischen Impulsen von einem ausgewählten Bereich des Körpergewebes an dem der Elektrodenkörper positionierbar ist, zu einem von dem ausgewählten Bereich abliegenden Wahrnehmungsort;

wobei die Oberflächentextur die Oberflächengröße der freiliegenden Oberfläche somit um einen Faktor von mindestens 5 vergrößert.

Revendications

1. Électrode implantable dans un patient, comprenant:

un corps d'électrode (20, 68, 76) constitué d'une structure de filament électriquement conducteur comportant une pluralité d'éléments de fibres allongées ayant des diamètres d'au moins cinq microns, lesdits éléments de fibres étant tassés à proximité immédiate les uns des autres, formant des passages multiples dans tout le corps de l'électrode et s'ouvrant vers l'extérieur du corps de l'électrode, par lequel une surface exposée des éléments de fibres allongées comporte une partie de surface intérieure le long desdits passages et définissant lesdits passages, et une partie de surface extérieure définissant la surface extérieure du corps de l'électrode, le volume occupé par les passages comprenant plus d'une moitié du volume total occupé par le corps d'électrode;

caractérisé par une texture de surface comprenant des irrégularités superficielles multiples formées sur presque toute la surface exposée des éléments de fibres allongées, afin d'augmenter sensiblement la zone de surface de ladite surface exposée par comparaison à une surface lisse équivalente d'un corps d'électrode de même dimension.

2. Électrode implantable selon la revendication 1, dans laquelle:

au moins certains des passages ont des diamètres dans la gamme de dix à cinquante microns, et la surface spécifique de ladite surface exposée est supérieure à une surface lisse équivalente d'un corps d'électrode de même dimension, d'un facteur d'au moins dix.

3. Électrode implantable selon la revendication 1 ou 2, dans laquelle:

ladite structure de filament comporte au moins un toron de fil métallique inséré dans une compresse.

4. Électrode implantable selon la revendication 3, dans laquelle:

ladite structure de filament est un toron unique dudit fil métallique, lesdits éléments de fibres (28, 70, 84) comprenant des parties du toron unique.

5. Électrode implantable selon la revendication 3 ou 4, dans laquelle:

lesdites irrégularités sont formées sous la forme d'une couche de texturation métallique (38, 50, 56) appliquée audit fil métallique.

6. Électrode selon la revendication 5, dans laquelle:

ladite couche de texturation métallique (38, 50, 56) consiste sensiblement en de l'aluminium, du platine ou du titane.

7. Électrode selon la revendication 5 ou 6, dans laquelle:

ladite couche de texturation (38, 50, 56) est appliquée par dépôt en phase vapeur après la formation de ladite compresse.

8. Électrode selon l'une quelconque des revendications 3 à 7, comportant en outre:

une sous-couche d'augmentation de l'adhérence (48, 54) entre ledit fil métallique et ladite couche de texturation.

9. Électrode selon la revendication 8, dans laquelle:

ladite sous-couche (48, 54) consiste sensiblement en du titane.

10. Électrode selon l'une quelconque des revendications 3 à 9, comportant en outre:

une couche de protection métallique inerte (42, 58) déposée sur ladite couche de texturation métallique.

11. Électrode selon la revendication 10, dans laquelle:

ladite couche de protection est formée d'un matériau catalytique ayant une faible énergie d'activation.

12. Électrode selon la revendication 11, dans laquelle:

ledit matériau catalytique consiste sensiblement en l'un des constituants suivants: le platine, le titane et un alliage platine-iridium.

13. Électrode selon la revendication 12, dans laquelle:

ledit matériau catalytique consiste sensiblement en du platine et comporte en outre

une couche de carbone (44, 60) déposée en phase vapeur sur ladite couche de platine.

14. Électrode selon l'une quelconque des revendications précédentes, dans laquelle:
lesdites irrégularités comprennent des nodules multiples ayant des diamètres moyens inférieurs à environ quatre microns.
15. Électrode selon la revendication 14, dans laquelle:
le diamètre moyen desdits nodules est de un à deux microns.
16. Électrode selon la revendication 15, dans laquelle:
lesdites irrégularités comportent en outre des évidements ayant un diamètre moyen d'environ un à deux microns.
17. Électrode selon l'une quelconque des revendications précédentes, dans laquelle:
lesdits passages ont des diamètres moyens dans la gamme d'environ dix microns à environ cent cinquante microns.
18. Électrode selon la revendication 17, dans laquelle:
lesdits passages ont des diamètres moyens dans la gamme de dix à cinquante microns.
19. Électrode selon la revendication 1, comportant en outre:
un conducteur électrique souple (18, 64) et une gaine diélectrique biocompatible souple (24, 66) entourant ledit conducteur sur presque toute sa longueur; et
un moyen de couplage (22, 74) pour joindre électriquement et mécaniquement le corps d'électrode au conducteur, ledit corps d'électrode étant tassé contre le moyen de couplage;
dans laquelle au moins certains des passages ont des diamètres dans la gamme de dix à cinquante microns.
20. Électrode selon la revendication 1, comportant en outre:
une première couche de torons (78, 80) entrelacés et mutuellement perpendiculaires formés d'un matériau bio-compatible et électriquement conducteur;
dans laquelle ledit corps d'électrode est réalisé sous la forme d'une seconde couche comportant ladite pluralité d'éléments (84) de fibres allongées contenus contre ladite première couche et lesdits passages multiples s'ouvrent sur ladite première couche; et

dans laquelle ladite texture de surface augmente ainsi la zone de surface d'un facteur d'au moins cinq.

- 5 21. Électrode de défibrillation de surface selon la revendication 20, comportant en outre:
une troisième couche de torons entrelacés mutuellement perpendiculaires (78, 80) formés d'un matériau biocompatible électriquement conducteur disposé à l'opposé de ladite Première couche, ladite seconde couche étant contenue entre les première et troisième couches.
- 10 22. Électrode selon la revendication 1, comportant en outre:
un conducteur (18, 64, 82) électriquement associé audit corps d'électrode pour transmettre des impulsions électriques d'une zone sélectionnée de tissu corporel sur lequel le corps d'électrode peut être mis en place, vers un lieu de détection éloigné de ladite zone sélectionnée;
dans laquelle ladite texture de surface augmente ainsi la zone de surface de ladite surface exposée d'un facteur d'au moins cinq.
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- 50
- 55

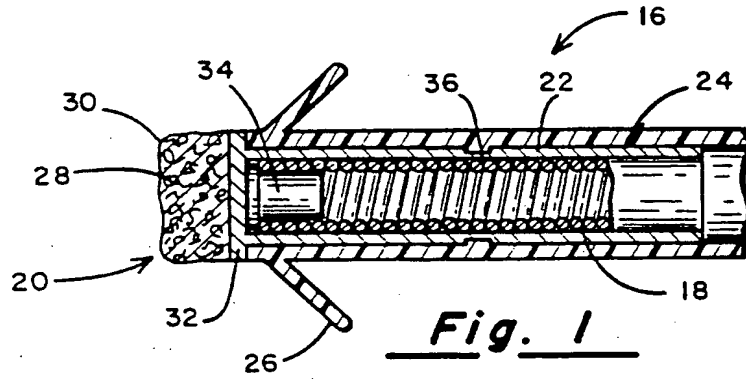


Fig. 1

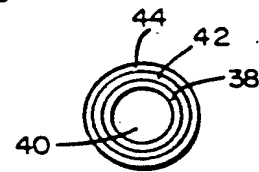


Fig. 4

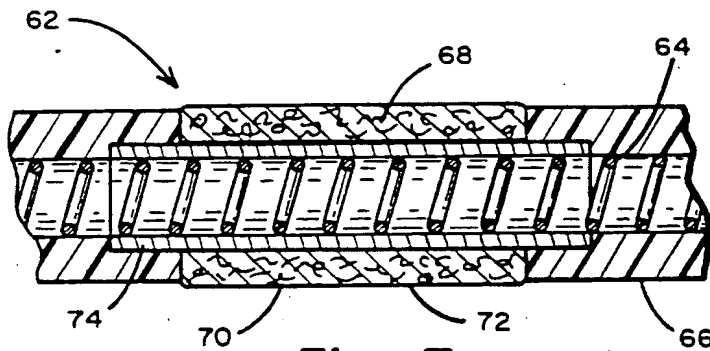


Fig. 7

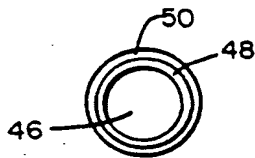


Fig. 5

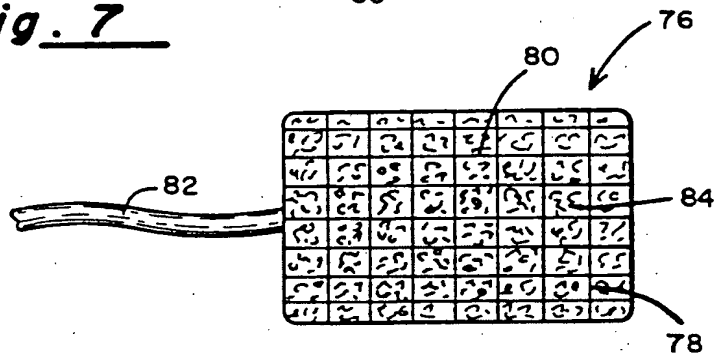


Fig. 8

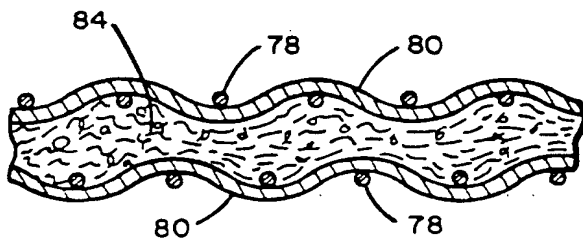


Fig. 9

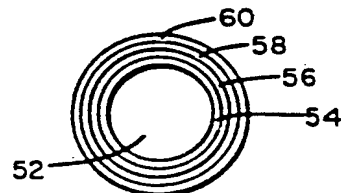
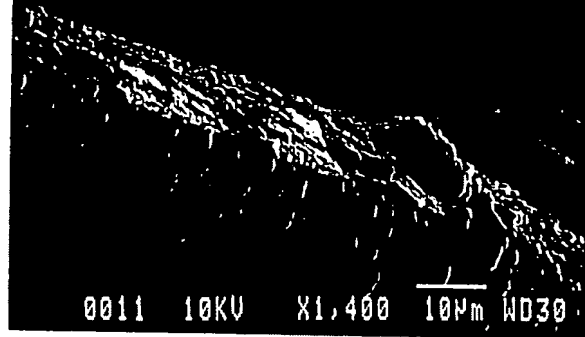


Fig. 6

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EP 0 453 117 B1

89-547 TEXTURED TIP



0011 10KV X1,400 10µm WD30

Fig. 3

SEI

89-849-IONYX-ELECTRODE TIP



0005 10KV X50 100µm WD30

Fig. 2